DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1999

5404 '00 JAN 13 P1:58

Thomas O. Henteleff
Kleinfeld, Kaplan and Becker
1140 Nineteenth Street, NW
Washington, DC 20036-6601

RE: #99P-0792

Dear Mr. Henteleff:

This is in response to your petition dated March 1, 1999, requesting that the Commissioner amend the prescription legend statement, required by 21 Code of Federal Regulations (CFR) §801.109(b)(1), to permit the use of an "Rx only" or "Rx" symbol as a substitute for the prescription legend statement.

You state that the "Rx" symbol effectively conveys the same message as that of a prescription legend statement, i.e., that a prescription is required to dispense the product. You also state that the substitution of the symbol "Rx only" for the required text would reduce clutter on labels, increase international uniformity and simplify labels, which could help reduce the incidence of medication errors that may be associated with the label and package design. Your request corresponds to the recent implementation of Section 126 of the FDA Modernization Act of 1997 (FDAMA), which amends section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). FDAMA authorizes the use of the "Rx only" symbol for the prescription legend statement in lieu of the prescription legend statement previously required for drugs.

FDAMA did not require any change to prescription device label requirements. As you note, prescription devices must bear a prescription legend statement; otherwise the agency would consider the device misbranded under section 502(f)(1) of the Act and prohibited from commercial distribution. Your request asks that we authorize this change by regulation to correspond to the statutory change implemented for prescription drugs.

We agree that an alternative to the current prescription device label requirement could convey the same message. An alternative to the prescription legend statement would reduce the burden on manufacturers, repackers, relabelers and distributors that face a variety of labeling requirements and changes. The agency, in its enforcement discretion, does not intend to object to the use of the statement "Rx only" as an alternative to the prescription device labeling statement in §801.109. We note that in your petition, the word "only" does not appear necessary. We disagree. The word "only" needs to immediately follow "Rx."

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We have published draft guidance entitled "Alternative to Certain Prescription Device Labeling Requirements." The draft guidance explains our policy on the use of a labeling alternative to the prescription device labeling statement. The agency's use of its enforcement discretion concerning this prescription labeling policy generates the benefits you seek without amending the prescription device legend statement. FDA will consider an amendment to its regulations following some experience with manufacturers' use of the alternative.

If you have additional questions regarding this matter, you may contact Mr. Casper E. Uldriks, Special Assistant to the Director, in our Office of Compliance at (301) 594-4692.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and
Radiological Health